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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,766	12/12/2003	David Chien	PP-20001.002	9349

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EXAMINER	
POHNERT, STEVEN C	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,766	CHIEN ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/21/04,9/20/04,10/26/04,6/13/05.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-19, in the reply filed on 7/6/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

2. The disclosure is objected to because of the following informalities: Page 17 last line references figure 14. There is no figure 14 in specification.

Appropriate correction is required.

Claim Objections

3. Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 does not encompass blood or blood products, but a device requiring a container, compartment, and section. Claim 19 is dependent on claim 1 and drawn to blood products comprising platelets. As blood products are not encompassed by claim 1, claim 19 is not further limiting.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-14, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Muir et al, (WO 1999/26724).

With regards to claim 1, Muir teaches a bodily fluid sample collection unit attached to at least one reaction chamber (see page 3 lines 17-23 and figure 5) for the screening of pathogens. The compartment for testing and the first section for holding sample to be tested are interpreted as being the same; as such the claimed device requires a container and compartment. The sample entry of figure 5 is interpreted as the container and compartments A to H are interpreted as the compartments or sections.

With regards to claim 2, Muir teaches a device that has a sample entry contiguous with compartments (see figure 5). The sample entry is interpreted as the container and compartments A to H are interpreted as the compartments or sections. The sample entry of figure 5 is contiguous with compartment A.

With regards to claim 3, Muir teaches the receptacle allows the reaction chamber to be completely sequestered (see page 10, line 10). Completely sequestered is interpreted as sealed, or separated for testing of instant application.

With regards to claim 4, Muir teaches compartments within the reaction chamber, that is separated by a barrier (see page 11 lines 16-18). Barrier is interpreted as a seal.

With regards to claim 5, Muir teaches the compartment barriers break under appropriate pressure (see page 12, lines 5-8). A seal breaking under appropriate pressure is interpreted as pressure sensitive seal.

With regards to claim 6, Muir teaches the reaction chamber has 2 or more compartments, which is interpreted as a plurality (see page 11 lines 16-18).

With regards to claim 7, Muir teaches a device that has a sample entry contiguous with compartments (see figure 5). The sample entry is interpreted as the container and compartments A to H are interpreted as the compartments or sections. The compartments A-H thus protrude from the side of the sample entry.

With regard to claim 8, Muir teaches a sample-containing unit comprising bodily fluid can be connected to the device allowing biological samples to flow from the sample-containing unit to the protruding compartments and be sealed (see figure 5, page 13, lines 8 and 9, page 11, lines 16-18).

With regards to claim 9, Muir et al teaches the receptacle or reaction container allows for complete sequestering (see page 10 line 10) and teaches this can be accomplished by valve switching or syringe emptying (see page 12 lines 27-29).

With regards to claim 10, Muir teaches in figure 5, at least a second (compartment A) and third sealed section (compartment B) that are contacted by breakable seals. The seals between the sample entry and compartment A are separate from the seal between compartment A and compartment B. Thus the sample entry is arranged in sealed contact with compartment A. Compartment A is arranged in seal contact with compartment B.

With regards to claim 11, Muir teaches a sample is placed in compartment A, the seal between compartment A and B is ruptured by pressure (see page 58 lines 15-19). Muir teaches the cells are lysed in compartment B (see page 58 lines 22-24). Muir further teaches that pressure is applied to the seal between compartments B and C; the seal is ruptured (see page 59 lines 4-5).

With regards to claim 12, Muir teaches compartment B contains lysis reagents (see page 58, lines 22-24). Muir further teaches lysing reagents include alkali, detergent, hypotonic solutions and combinations (see page 14 lines 8-9). The buffer is thus interpreted as lysing reagents.

With regards to claim 13, Muir teaches compartment C contains labeled nucleic acid probes complementary those of interest (see page 59 line 7-9) for testing transferred contents from compartments A and B. The nucleic acids of Muir are interpreted as being test reagents.

The reagents of claims 14 and 17 are interpreted as being components of the biological storage device.

With regards to claim 14, Muir teaches the use of PCR amplification to detect a polynucleotide sequence (see page 16, lines 22-23). The polymerase used in PCR is a catalytic enzyme and the primers used for PCR are interpreted as a reporter sequence.

With regards to claim 17, Muir teaches PCR in which a primer is covalently attached to a solid support (see page 18 Lines 19-20). The primer covalently attached to a solid support is an immobilized reporter sequence.

6. With regards to claim 19, Muir teaches a bodily fluid sample collection unit attached to at least one reaction chamber (see page 3 lines 17-23) for the screening of pathogens. Claim 19 is drawn to blood comprising platelets, however blood is not claimed. Claim 19 is thus not further limiting of claim 1 and was given to patentable weight. Muir teaches bodily fluids include blood (see page 3 line 8), which comprise platelets. Muir further teaches assays to determine bacterial growth in platelets (page 75, lines 25-26) using probes to 16S rRNA (see page 76 lines 7-8).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al, (WO 1999/26724) in view of Shih, et al (US Patent 5589332).

Claim 14 is rejected as directed to ribozymes as catalytic molecule. The reagents of claims 14-17 are interpreted as being components of the biological storage device.

Muir teaches devices that have reaction chambers filled by flow from the storage container (see page 5 lines 21-25, figures 2 and 3) for the testing of bacteria, virus, fungi or parasitic contamination in biological samples (see page 2, lines 19-21). Muir teaches the receptacle which allows the reaction chamber to be completely sequestered. Muir teaches compartments within the reaction chamber, that are

separated by a barrier (see page 11 lines 16-18). Muir teaches the compartment barriers break under appropriate pressure (see page 12, lines 5-8. Muir teaches in figures 11 and 12, at least a second and third sealed section that are contacted by breakable seals. These contacts are different from the contact and seal of the first sealed section. Muir teaches sample is place in compartment A, the seal between compartment A and B is ruptured by pressure (see page 58 lines 15-19). Muir teaches the cells are lysed in compartment B (see page 58 lines 22-24). Muir further teaches that pressure is applied to the seal between compartments B and C; the seal is ruptured (see page 59 lines 4-5). Muir teaches compartment B contains lysis reagents (see page 58, lines 22-24). Muir further teaches lysing reagents include alkali, detergent, hypotonic solutions and combinations (see page 14 lines 8-9). Muir teaches compartment C contains labeled nucleic acid probes complementary those of interest (see page 59 line 7-9) for testing transferred contents from compartments A and B. Muir teaches the use of PCR amplification to detect a polynucleotide sequence (see page 16, lines 22-23). Muir does not teach a catalytic molecule is an inactivated ribozyme (claim 15) and reporter sequence is RNA (Claim 16). Muir further does not teach the immobilization of a ribozyme or RNA reporter on a solid support (claim 17).

However, Shih teaches an activated ribozyme complex which includes the ribozyme, co-target molecule (RNA) and disease target molecule (see column 5, lines 1-3) for the diagnostic detection of clinical samples (see column 5 line 65) pathogenic agents, which include viruses, bacteria, or fungi (see column 8 lines 53-54). Shih further teaches use of ribozymes in diagnostics provide high specificity and simple,

sensitive and quantitative assays (see column 4 lines 44-46). As Shih teaches an activated ribozyme requires a ribozyme, a co-targeting molecule, and target molecule, a complex of a ribozyme and targeting molecule would be inactive (claim 15). Shih further teaches the co-target is a RNA molecule that can be anchored to a solid support (see column 5 lines 11-14) (claims 16 and 17) to allow quantification (see column 3, lines33-34).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to include the diagnostic ribozymes and RNA co-targets of Shih in the blood storage and testing device of Muir because both Muir and Shih teach testing of blood for pathogens. Shih further teaches ribozymes provide a highly specific simple quantifiable method for detecting virus, fungi, or bacteria in clinical samples. One of ordinary skill in the art would be motivated to improve the blood-testing device of Muir with the diagnostic ribozymes and co-targeting RNA of Shih because the diagnostic ribozymes and co-targets allow a simple sensitive and quantifiable assay of pathogens in clinical samples. The ordinary artisan at the time the invention was made would be further motivated to combine the blood testing device of Muir with the covalently attached co-target of Shih, because it would improve quantitation of clinical sample pathogen assays. The ordinary artisan would be motivated to covalently attach the co-target, because Shih teaches it would allow quanititation.

9. Claim18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al, (WO 1999/26724) and Shih, et al (US Patent 5589332) as applied to claims 14-17 above, and further in view of Chen et al (US Patent 6251599).

The teachings of Muir and Shih are set forth above.

However, Chen et al teach lyophilized nucleic acid increases the concentration of nucleic acids (see column 24 lines 23-25). Chen teaches nucleic acids include RNA (see column 4 line 39). Lyophilization of RNA co-target or the inactive ribozyme increases the concentration of the lyophilized molecule.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to lyophilize the co-target RNA and inactive ribozymes of the Muir and Shih biological sample storage and reaction device to concentrate the lyophilized molecules as taught by Chen. The ordinary artisan would be motivated because Chen teaches lyophilization concentrates the ribozyme and co-target RNA.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al, (WO 1999/26724) in view of Chen et al (US Patent 6251599)

The blood storage and analysis device as taught Muir has a storage compartment and reaction chamber, with multiple sections separated by breakable seals. The Muir biological storage and testing device has a DNA and primer test sequences. The device of Muir does not have lyophilized catalytic or reporter molecule.

However, Chen et al teaches lyophilization of a nucleic acid increases the concentration of nucleic acids (see column 24 lines 23-25). Chen teaches nucleic acids

include DNA (see column 4 line 39). Lyophilization of DNA primers increases the concentration of the DNA primers.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to concentrate the DNA primers of Muir's biological storage and testing device by lyophilization as taught by Chen. The ordinary artisan would be motivated because Chen teaches lyophilization increases the concentration of the DNA primers.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1, 6, and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5 of copending Application No. 10733767. Although the conflicting claims are not identical, they are not patentably distinct from each other because co-extensive in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 of instant application is drawn to a blood storage device and a compartment for testing. Claim 1 of application 10733767 a biochip unit and collection unit. The testing compartment of instant application broadly interpreted to encompass a biochip unit. The blood storage device is interpreted to encompass a storage device.

Claim 1 of instant application is drawn to a blood storage device and a compartment for testing. Claim 24 of application 10733767 a biochip unit and collection bag. The testing compartment of instant application broadly interpreted to encompass a biochip unit. The blood storage device is interpreted to encompass a storage device.

Claim 6 of instant application is drawn a biological storage device having a plurality of compartments. Claim 5 of application 10733767 is drawn to a sequentially arranged biochip unit, which is interpreted as a plurality of compartments.

Claim 19 of instant application is drawn to the blood products, which comprise platelets. Claim 1 of application 10733767 is drawn to blood, which comprises platelets.

Summary

No claims are allowed over prior art cited.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Steven Pohnert

JEHANNE SITTON
PRIMARY EXAMINER
9/11/06